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Hazard Evaluation Division, Standard Evaluation Procedure - Non-Target Plants Vegetative Vigor - Tiers 1 and 2

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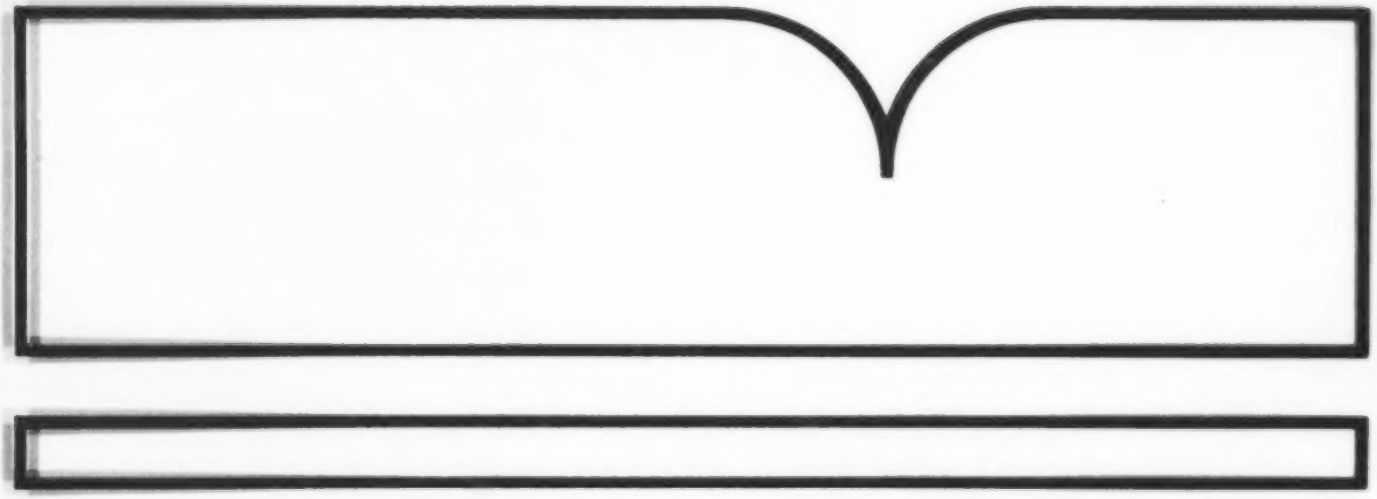

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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

NON-TARGET PLANTS: VEGETATIVE VIGOR - TIERS 1 AND 2

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16. Abstract (Limit: 200 words)

The Standard Evaluation Procedure for Non-Target Plants: Vegetative Vigor - Tiers 1 and 2, a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Standard Evaluation Prodedure (SEP), prescribes the evaluation criteria and procedures to assess this pesticide phytotoxicity study that the US Environmental Protection Agency recommends to support the registration of manufacturing-use and formulated end-use products. This SEP, in conjunction with the Pesticide Assessment Guidelines, Subdivision J. is designed to aid data reviewers in their evaluation of vegetative vigor studies submitted by registrants. A summary of the rulemaking phytotoxicity test requirements can be found in 40 CFR Part 158. The study results contained in the evaluation procedure together with environmental fate and efficacy data are used to assess the potential hazard of pesticides to terrestrial and aquatic nontarget plants.

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NON-TARGET PLANTS: VEGETATIVE VIGOR - TIERS 1 AND 2

I. INTRODUCTION

A. Purpose of the Standard Evaluation Procedure

This Standard Evaluation Procedure is designed to aid Ecological Effects Branch (EEB) data reviewers in their evaluations of preliminary (Tier 1) laboratory vegetative vigor studies submitted by registrants in the assessment of pesticide effects on non-target plants. This document is also designed to aid EEB reviewers in their evaluations of laboratory/greenhouse/small field plot (Tier 2) vegetative vigor studies submitted by registrants for the same purpose.

B. Background Information

Vegetative vigor studies are designed to provide phytotoxicity data on a pesticide. These phytotoxicity data are needed to evaluate the effect of the level of pesticide exposure to non-target terrestrial plants and to assess the impact of pesticides on endangered and threatened plants as noted under the Endangered Species Act. The preliminary level (Tier 1) study evaluates the effect of the maximum exposure level while the greenhouse/laboratory/small field plot (Tier 2) study evaluates the effects of differing exposure levels. Where a phytotoxic effect is noted in one or more plants, further terrestrial vegetative vigor studies may be required. These studies are required by 40 CFR § 158.150 to support the registration of any pesticide intended for outdoor use under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

Pesticides with outdoor use patterns that do not readily release the pesticide to the environment do not have to be evaluated using this phytotoxicity test. These use patterns include tree injection, subsurface soil applications, recapture systems, wick applications, and swimming pool uses. If any of these use patterns do readily expose non-target plants to the pesticide, as through vapors, the pesticide phytotoxicity potential may need to be evaluated.

C. Objectives of Vegetative Vigor Tests

1. Tier 1 Test

The objective of the Tier 1 vegetative vigor test is to determine if a pesticide exerts a detrimental effect to plants during the vegetative growth period of their development as a result of post-emergent foliar or soil applications. The test is performed on species from a cross-section of the non-target terrestrial plant population that have been historically used for this type of testing and, therefore, have known types of responses. This is a maximum dose test designed to evaluate the phytotoxic effects of the pesticide quickly at the one dose.

2. Tier 2 Test

The objective of the Tier 2 vegetative vigor test is to determine if a pesticide exerts a detrimental effect to plants during the vegetative growth period of their development. The test is performed on species from a cross-section of the non-target terrestrial plant population that have been historically used for this type of testing and, therefore, have known types of responses. This is a multiple dose test designed to evaluate the phytotoxic effects of the pesticide over a wide range of anticipated pesticide quantities as may be found in the environment.

II. INFORMATION TO BE SUPPLIED

The registrant's report on vegetative vigor studies should include all information necessary to provide: 1) a complete and accurate description of the laboratory/greenhouse treatments and procedures, 2) sampling data and phytotoxicity rating, 3) data on storage of the plant material until analysis, if so performed, 4) any chemical analysis of the plant material as to chemical content, if so performed, 5) reporting of the data, rating system and statistical analysis, and 6) quality control measures/precautions taken to ensure the fidelity of the operations.

A guideline of specific information that should be included in the registrant's report on vegitative vigor studies is provided in Appendix 1 of this document. The lists of requested information and reviewer aids are derived from the Pesticide Assessment Guidelines, Subdivision J: Hazard Evaluation of Non-Target Plants, which is complemented by this Standard Evaluation Procedure.

III. DATA INTERPRETATION

The acceptability of the study results will depend upon whether the test requirements/standards are followed. If a deviation is made, a determination must be made as to whether the deviation has changed the quality of the results in such a manner that the results cannot be extrapolated to the natural environment. There should be little or no deviation from the liberalized standards prescribed in this study.

The results of the phytotoxicity test of the chemical with respect to the quantity applied post-emergent to the foliage or soil are important. The concentration of the chemical in the carrier is important in that stronger concentrations than normally used can lead to burning and necrosis or undesired growth. Subtoxic concentrations, on the other hand, may cause unwanted rapid growth.

Plants can recover from certain types of injury that will have little or no effect on the esthetic or economic value of the plant(s)

tested or to which an evaluation is made. Therefore, it is important that a minimum of two weeks of observations be made after application of the pesticide; three to four weeks are preferable.

A decision point to proceed on to the next higher test is a 25% detrimental effect, i.e., a 25% reduction or over-enhancement in plant growth or injury as compared to the untreated controls. This level is considered to be that point at which the plants will not recover to their full esthetic value, economic value, or reproductive potential as in the case of the maintenance of the endangered or threatened species.

IV. THE DATA EVALUATION PROCESS

Upon careful examination of the information/data supplied by the registrant in his submission to the Agency, the reviewer shall evaluate the data as follows.

A. Identify Data Gaps

Using Appendix 1 of this document as a guide, the reviewer should look for data gaps - omissions in the information supplied by the registrant in his report. These should be duly noted in the reviewer's report, and a judgment made as to which are considered significant enough to adversely affect the review process. Those so identified should be communicated back to the registrant by the Product Manager for corrective action.

B. Assess the Appropriateness and Adequacy of the Data

The data reviewer then considers the appropriateness, i.e., the intended use pattern, and adequacy of the data/information that has been supplied. Appendix 1 of this document is a useful guide to the various parameters that need to be considered. Appendix 2 provides specific questions that should be answered by the reviewer during the study evaluation process. Statistical treatments of the data should be independently verified and the quality control precautions noted.

As an adjunct to these, the reviewer should draw upon the technical guidance in the reviewer aids materials that are available. (See also the recommended references in Subdivision J - Hazard Evaluation: Non-Target Plants.) A listing of additional source materials is located in the References section of this document.

In addition to the data gaps noted above, any perceived deficiencies in the data/information supplied should be identified. A statement as to these deficiencies should be made in the reviewer's report and corrective action to resolve them should be provided. This information can be relayed to the registrant by the Product Manager for appropriate action.

C. Report Preparation

The Agency reviewer prepares a standard review report following the standard format for preparation of scientific reviews as provided in Appendix 3 of this document. All important information provided by the registrant including the methodology and results should be summarized in order that future evaluations can be made. The results may be expressed in the form of tables where specific values are related. Figures (graphs) may be provided but are not to be the sole source of the values needed for future evaluations.

D. Conclude if the Requested Action is Supportable

Lastly, the reviewer considers the results of the vegetative vigor studies and makes a judgment as to whether they support the requested registration action of the data submitter. If the data are not supportive, possible alternative action(s) that may be taken by the registrant, such as label modifications, are suggested. If deficiencies/omissions exist in the submitted data, the reviewer may have to defer judgment until such time as appropriate corrective action has been rendered by the registrant.

APPENDIX 1

INFORMATION REQUESTED OF THE REGISTRANT

The registrant's report on preliminary vegetative vigor studies should include all information necessary to provide: 1) a complete and accurate description of the laboratory/greenhouse/field treatments and procedures, 2) sampling data and phytotoxicity rating, 3) data on storage of the plant material if so performed, 4) any chemical analysis of the plant material as to chemical content, 5) reporting of the data, rating system, and statistical analysis, and 6) quality control measures/precautions taken to ensure the fidelity of the operations.

Specifically, each laboratory/greenhouse/small field plot vegetative vigor report should include the following information.

I. General

° Cooperator or researcher (name and address), test location (county and state; country, if outside of the U.S.A.), and date of study;

° Name (and signature), title, organization, address, and telephone number of the person(s) responsible for planning/supervising/monitoring;

° Trial identification number;

° Quality assurance indicating: control measures/precautions followed to ensure the fidelity of the phytotoxicity determinations, record-keeping procedures, and availability of logbooks; skill of the laboratory personnel; equipment status of the laboratory or greenhouse; degree of adherence to good laboratory practices; and degree of a herence to good agricultural practices in maintaining healthly plants; and

° Other information the registrant considers appropriate and relevant to provide a complete and thorough description of the test procedures and results.

II. Test Substance (Pesticide)

° Identification of the test pesticide active ingredient (ai) including chemical name, common name (ANSI, BSI, ISO, WSSA), and Company developmental/experimental name;

° Active ingredient percentage in the technical grade material or in the manufacturing-use product, if the technical grade material is unavailable for test purposes;

° Solvent used to dissolve and apply the pesticide if the pesticide is insoluble in water or other intended carrier;

° Dose rate(s) in terms of active ingredient per area of land or of leaf (if leaf-area-index is provided);

° For Tier 1, dose rate(s) in terms of the maximum label rate, or if the registrant has shown that the maximum quantity that will be present in the non-target area is significantly less than the maximum label rate, the dose equal to or no less than three times that maximum environmental quantity;

° For Tier 2, dose rate(s) in terms of less than the maximum label rate, with dosages in a geometrical progression of no more than two-fold and with subtoxic (< EC_{50} level) and non-toxic (no-observable-effect-level) concentrations;

° Method of application including equipment type; and

° Number of applications.

III. Plant Species

° For Tier 1, identification of the six dicotyledonae species and four monocotyledonae species with family identification. The six dicots are to be of at least four different families and the moncots of at least two families. Soybeans, corn, and a dicot root crop like carrot are the required species. The proposed species and families as originally provided in Subpart J of the proposed guidelines [FR notice of 3 November 1980] are given below and are acceptable for the laboratory/greenhouse vegetative vigor test.

Family	Species	Common
Solanaceae	Lycopersicon esculentum	Tomato
Cucurbitaceae	Cucumis sativus	Cucumber
Compositae	Lactuca sativa	Lettuce
Leguminosae	Glycine max (Innoculated with Rhizobium japonicum)	Soybean
Cruciferae	Brassica oleracea	Cabbage
Umbelliferae	Daucus carota	Carrot
Gramineae	Avena sativa	Oat
Gramineae	Lolium perenne	Perennial Ryegrass
Gramineae	Zea mays	Corn
Amaryllidaceae	Allium cepa	Onion

° For Tier 2, identification of the plant species tested including those phytotoxically affected in the Tier 1 test;

° Identification of the cultivar(s) of the plant species or assignment of an identification number of the cultivar used and the plant source;

° Identification of the number of replicates and the number of plants per replicate per dose; and

° Identification of the date of planting, date of pesticide application, and date of phytotoxicity rating or harvest.

IV. Site of the Test

° Site description of the vegetative vigor study such as the type of growth chamber, greenhouse, or field (small field plots);

° Location of the test site;

° Climatological data during the test (records of applicable conditions for the type of site, i.e., temperature, thermoperiod, rainfall or water regime, light regime - intensity and quality, relative humidity, wind speed);

° Field lay-out (for small field plots), e.g., size and number of control and experimental plots; number of plants per plot/unit area;

° Pot, plate or row density of plants;

° Cultural practices such as cultivation and irrigation; and

° Substrate characteristics (name/designation of soil type and its physical and chemical properties, including pH and percent organic matter).

V. Results

° Phytotoxicity rating (including a description of the rating system) for each plant or population in the test;

° Reporting of weight, height, or other growth parameters that may have been measured to ascertain toxic effects of the pesticide upon the plants with dates of observations; and

° Statistical analysis of the results including an environmental or effective concentration effect (EC) value. (Note, with only one dose level in Tier 1, there will be only a percent effect level at a specific concentration which is then compared to 25% of the growth [mass or rate] of the control.)

VI. Evaluations

° For Tier 1 studies, determination as to whether Tier 2 studies would be required due to phytotoxic effects noted in one or more of the tested species.

° For Tier 2 studies, determination as to whether Tier 3 tests (terrestrial field study) would be required due to phytotoxic effects noted on one or more of the tested species.

APPENDIX 2

SPECIFIC QUESTIONS FOR THE REVIEWER

The following questions are provided to aid the reviewer in performing the standard evaluation procedure in a scientific manner and in acquiring the necessary information to complete a standard format for preparation of scientific reviews.

I. General

° Was the name of the cooperator or researcher (name and address), test location (county and state; country, if outside of the U.S.A.), and date of study provided?

° Was the name (and signature), title, organization, address, and telephone number of the person(s) responsible for planning/supervising/monitoring and, for small field plot studies, applying the pesticide provided?

° Was the trial identification number provided?

° Were quality assurance control measures/precautions indicated?

II. Test Chemical

° Is the test chemical being used the technical grade, or if not available, the manufacturing-use product with the highest percentage of active ingredient?

° Is the active ingredient percentage or degree of purity of the chemical given?

° If a solvent was used, was it used at concentrations that were not phytotoxic and was a solvent control used?

° Is the dose given in quantity per unit area (of plant or land surface) or in tank concentration?

° For Tier 1, was the dose equal to or greater than the maximum label rate, or if registrant has shown that the maximum quantity that will be present in the non-target area is significantly less than the maximum label rate, was the dose equal to or no less than three times that maximum environmental quantity?

° For Tier 2, was the maximum dose less than the maximum label rate?

° For Tier 2, were the additional dosages of a geometric progression of no more than two-fold, e.g., 0.1, 0.2, 0.4, 0.8, 1.6 kg/ha?

° Were a subtoxic (EC_{50} level) and a non-toxic (no-observable-effect-level) concentration evaluated?

III. Test Species

° For Tier 1, were at least ten different species tested?

° For Tier 1, were the ten species split between monocots and dicots, four and six, respectively?

° For Tier 1, were the ten species from six different families and the family names provided?

° For Tier 1, were two of the species tested soybeans and corn and was the third species a dicot root crop?

° For Tier 2, were at least those species that were phytotoxically affected in Tier 1 tested?

° Where various cultivars could be used such as in the case of most agronomic and horticultural plants, were cultivar or varietal names provided?

° Were the plant sources provided?

° Were there at least three replicates with five plants per replicate for each dose level?

° Were the plants at least one week to four weeks post-emergent and in the exponential stage of growth at the time of application?

° Were the plants healthy and not in a state of stress?

° Were endangered or threatened plant species not used?

IV. Test Procedures

° Was the test site specified, i.e., greenhouse, growth chamber, or small field plot?

° Were the environmental conditions that prevailed during the test (temperature and thermoperiod, light regime - intensity and quality, relative humidity, rainfall or watering regime, wind) provided as appropriate for the site?

° Were the environmental conditions that prevailed during the test those most favorable and most typical to the growth of the plants used? Were these conditions referenced?

° Was the test duration at least two weeks in length?

° Were observations taken at least weekly?

° Was the method of pesticide application including the type of application equipment employed given?

V. Reporting

° Were the detrimental effects reported as severity of phytotoxicity, growth inhibition, etc. (rating or percentage)?

° If a rating system was used, was an explanation provided?

° Were abnormal changes in growth, development and/or morphology reported as compared to the controls or "normal" plants?

° Though not required, were direct measurements of height and weight of the plants provided?

° Were the results statistically analyzed? Note that care should be taken in interpreting the statistical results where the sample size is small.

VI. Evaluation

° Were the results tabulated to indicate a percentage effect level (EC value) for each species as compared to the untreated control plants?

° For Tier 1 studies, was a determination made as to whether Tier 2 tests should be performed if any of the Tier 1 species were detrimentally affected (greater than 25% detrimental effect on growth)?

° For Tier 2 studies, were 25 and 50 percent detrimental effect levels determined for those plant species of Tier 1 that showed a phytotoxic effect to the chemical?

° For Tier 2 studies, was a determination made as to whether Tier 3 tests (terrestrial field study) should be performed if any of the Tier 2 species were detrimentally affected (greater than 25% detrimental effect on growth)?

APPENDIX 3

SAMPLE STANDARD FORMAT FOR PREPARATION OF SCIENTIFIC REVIEWS

The following format shall be used in documenting the review of the Subdivision J - Hazard Evaluation: Non-Target Plants - Tier 1 and Tier 2 Vegetative Vigor Studies.

Chemical: (Common Name)

Formulation: (Percent Active Ingredient)

Study/Action: (Purpose of the Submission)

Study Identification:

(Subdivision J Test Title)
(Reference or Registrant Data Information with Study Number)
(EPA Accession Number)

Reviewer: (Name and Address of Reviewer; Date of Review)

Approval: (Quality Control Reviewer)

Conclusions: (Summary and Conclusion of Tests)

Acceptability and Recommendations:

(Decide as to (1) the scientific validity of the study and (2) compliance to the Subdivision J - Vegetative Vigor Tier 1 and Tier 2 Studies.)

Background: (Introductory Information and Directions for Use)

Discussion:
1. Study Identification
2. Materials and Methods
3. Reported Results
4. Reported Conclusions
5. Reviewer's Interpretation of Results and Conclusion

REFERENCES

Truelove, B., ed. 1977. Research Methods in Weed Science. Southern Weed Science Society. Auburn, AL: Auburn Printing, Inc.

Other scientific articles on vegetative vigor may be found in the following journals:

Agronomy Journal
Environmental Science and Technology
Journal of Environmental Quality
Soil Science and Plant Nutrition
Weed Science